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RUTHIA HE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA,

CASE NO. 3:24-cr-00329-CRB

Plaintiff.

V.

RUTHIA HE, A/K/A RUJIA HE, and
DAVID BRODY.

**DEFENDANT RUTHIA HE'S REPLY RE:
APPLICABLE LEGAL STANDARD FOR
21 U.S.C. §§ 841(a), 846 AND REQUESTED
JURY INSTRUCTIONS RE: SAME**

Defendants.

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1 Contrary to the Government’s claim, nothing in *Ruan v. United States*, 597 U.S. 450
2 (2022), changed the well-established conjunctive standard that applies in this Circuit to a
3 Controlled Substances Act (CSA) prosecution involving licensed medical professionals, or this
4 Court’s well-founded concern in *Napoli* about confusion over the dividing line between criminal
5 and non-criminal conduct, which animated its jury instruction distinguishing between intentional
6 malpractice and the higher benchmark required for criminal liability. Instead, *Ruan* simply
7 *confirmed* this Circuit’s precedent on the *mens rea* requirement of 21 U.S.C. § 841(a)—namely,
8 that the requisite proof is *knowledge or intent* that the prescription was unauthorized, not merely
9 that a prescription was in fact not authorized.

10 Ms. He therefore requests that this Court instruct the jury, as it did in *Napoli*, that “it is not
11 enough for the United States to prove that a practitioner committed malpractice, intentional or
12 otherwise; rather, the United States must prove that the physician used his prescription-writing
13 powers *as a means to engage in illicit drug dealing and trafficking.*” See Ex. A (*Napoli* Jury
14 Instructions, ECF 1056, at 17) (quoting *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir.
15 2006)) (emphasis added) (hereinafter “*Napoli*-based malpractice instruction”)¹; *see also* ECF 380
16 at 65. As this Court reasoned at the *Napoli* charge conference, in electing to charge the jury
17 accordingly: “I’m concerned about it [the applicable language for the jury charge] because you
18 can’t have a defendant, a doctor, convicted … *if he committed malpractice, intentional or*
19 *not...that’s not what this case is about. What this case is about is essentially drug pushing...*If
20 you haven’t proven that, you don’t deserve to win....” See ECF No. 478 at Ex. A (Tr. at 4512:14-
21 19) (emphases added). So too here.

22 Ms. He further requests, in addition to the *Napoli*-based malpractice instruction and
23 consistent with this Circuit’s precedent and the tentative that the Court provided today, that the
24 jury be instructed that the requisite proof is knowledge or intent to prescribe *both* “without a
25 legitimate medical purpose” *and* “outside the usual course of professional practice,” if the Court

26 _____
27 ¹ The *Napoli* instructions are reattached here to include pertinent portions missing from ECF 478
28 at Ex. A.

1 adopts the regulatory language in 21 C.F.R. § 1360.04(a) as providing the relevant standard for
2 authorization under the Controlled Substances Act (CSA). *See* ECF No. 478 at 8-10.²

3 Ms. He also asks (and preserves her request for review) that the Court remove the terms
4 “legitimate” and “usual” from the instructions. Eliminating these modifiers together with the
5 *Napoli*-based malpractice instruction properly enforces the critical distinction between
6 malpractice—“intentional or otherwise”—and the higher threshold for criminal liability. *See* ECF
7 478 at 5-8.

8 **1. The Court Should Give Its *Napoli*-based Malpractice Instruction.**

9 As Ms. He has explained, the dividing line between criminal and non-criminal conduct in
10 this context is knowledge or intent to act as a drug dealer rather than a medical provider. *See* ECF
11 478 at 3-5. Thus, both the Ninth Circuit and this Court have held that that “the jury must make a
12 finding of intent not merely with respect to distribution, but also with respect to the doctor’s intent
13 to act as a pusher rather than a medical professional.” *Feingold*, 454 F.3d at 1008. This Court gave
14 instructions to that effect in *Napoli* and it should do so again here. ECF No. 478 at Ex. A; *see also*
15 ECF 380 at 65.

16 The Government has not only conceded—but originally proposed an instruction for §
17 841(a) here—that “[i]t is not enough for the United States to prove that a practitioner committed
18 malpractice, intentional or otherwise.” ECF 380 at 60: 13-14. Although the Government does
19 not, and cannot, dispute that premise, it now claims that the Court’s *Napoli* instruction is
20 “unnecessary” on the theory that *Ruan*’s clarification of the *mens rea* standard sufficiently ensures
21 that defendants will not be convicted for malpractice. *See* ECF No. 483, at 7:17-28. Not so. *Ruan*

22

23 ² On the issue of the *mens rea*, however, the Court’s tentative altered the *Napoli* language which
24 required proof of an agreement to distribute controlled substances “by means of a prescription
25 issued by a physician not for a legitimate medical purpose and not in the usual course of
26 professional practice and *knowing and intending* that the distribution was by means of a
27 prescription issued by a physician not for a legitimate medical purpose and not in the usual course
of professional practice.” *See* Ex. A at 19 (emphasis added). The placement of the italicized *mens
rea* language is now required by *Ruan* as well as *Feingold* to ensure that the jury find that the
defendant knew or intended that the prescription was unauthorized, not merely that a prescription
was in fact not authorized.

1 merely confirmed the *mens rea* requirement of § 841(a) in this Circuit. *Cf. Ruan*, 597 U.S. at 454
2 (“We hold that the statute’s ‘knowingly or intentionally’ *mens rea* applies to authorization.”) *with*
3 *Feingold*, 454 F.3d at 1008 (“[T]he jury must make a finding of *intent* not merely with respect to
4 distribution, but also with respect to the doctor’s intent to act as a pusher rather than a medical
5 professional.”) (emphasis added); *id.* at 1010. Consequently, nothing has changed since *Feingold*
6 about the risk that the jury will confuse the criminal prohibition with a negligence standard—
7 especially in a case like this one. This Court’s “concern[]” that “you can’t have a defendant, a
8 doctor, convicted … if he committed malpractice, intentional or not…[w]hat this case is about is
9 essentially drug pushing” remains the same live and pressing issue that it was at the time of *Napoli*.
10 *See* ECF No. 478 at Ex. A (Tr. at 4512:14-19).

11 Moreover, Ms. He is not, as the Government claims, attempting to create “drug dealing”
12 as a separate element of proof. ECF No. 483 at 5:10-13. Rather, the purpose of the *Napoli*-based
13 malpractice instruction is to give effect to the fact that the CSA “bars doctors from using their
14 prescription-writing powers as a means to engage in illicit drug dealing and trafficking as
15 conventionally understood,” but does not “regulate the practice of medicine [more] generally.”
16 *Gonzales v. Oregon*, 546 U.S. 243, 270 (2005); *see also Ruan*, 597 U.S. at 458 (explaining that
17 “authorization plays a ‘crucial’ role in separating innocent conduct—and, in the case of doctors,
18 socially beneficial conduct—from wrongful conduct”). Since it is undisputed that intentional
19 malpractice is *not* the governing standard, and this is a case rife with potential confusion on that
20 issue, the jury should be expressly instructed to that effect, just as this Court did in *Napoli*.

21 **2. The Standard is Conjunctive.**

22 The CSA criminalizes the distribution of controlled substances “except as authorized.” 21
23 U.S.C. § 841(a). Ninth Circuit precedent provides that in a CSA case, proof that a defendant issued
24 “unauthorized” prescriptions requires proof of knowledge or intent to prescribe “outside the usual
25 course of professional practice *and* without a legitimate medical purpose.” *Feingold*, 454 F.3d at
26 1008.
27

1 The Government claims that *Ruan*, 597 U.S. at 450, supports a disjunctive reading of §
2 841’s authorization requirement. *See* ECF No. 380 at 47:7-19; *see also* ECF No. 483 at 10:14-
3 12:28. That is simply wrong. As the Government itself acknowledges, “*Ruan* did not directly
4 address the disjunctive versus conjunctive issue”—and therefore could not even purport to
5 overrule well-established Ninth Circuit precedent on this issue. *See* ECF No. 380 at 47:17.

6 The question presented in *Ruan* concerned only the statute’s *mens rea* requirement. *Ruan*,
7 597 U.S. at 454 (“The question before us concerns the state of mind that the Government must
8 prove to convict these doctors of violating the statute.”). And the holding in *Ruan* was confined
9 to that specific question. *See id.* (“We hold that the statute’s “knowingly or intentionally” *mens*
10 *rea* applies to authorization.”). Accordingly, longstanding Ninth Circuit precedent on the *mens*
11 *rea* requirement of § 841(a) was only confirmed by the Court’s decision.

12 Indeed, as discussed below, *no court of appeals has interpreted Ruan to alter Circuit*
13 *precedent on the requirement of proof in the conjunctive or to permit disjunctive proof where it*
14 *did not before*. This Court therefore should instruct the jury, consistent with this Circuit’s
15 precedent and *Napoli*, that conjunctive proof is required. That is especially so because the
16 Government’s contrary interpretation—under which “legitimate medical purpose” and “usual
17 course of professional practice” would impose two freestanding, alternative routes to liability—
18 would lower the burden of proof and risk criminalizing intentional malpractice, which the
19 Government agrees is an impermissible predicate for a conviction. *See* ECF 380 at 60: 13-14 (“It
20 is not enough for the United States to prove that a practitioner committed malpractice, intentional
21 or otherwise”).

22 **a. *Ruan* Confirmed Ninth Circuit Precedent.**

23 The Government suggests that *Ruan* supports its disjunctive construction because the
24 district court in that case had given a disjunctive instruction. *See* ECF No. 483 at 11:14-17. But
25 the Supreme Court simply did not address the conjunctive/disjunctive question, as the Government
26 concedes. ECF No. 380 at 47:17; ECF No. 483 at 11:12. The Government nonetheless observes
27 that *Ruan* characterized the prongs as “objective criteria” that define “the scope of a doctor’s

1 prescribing authority.” *Ruan*, 597 U.S. at 467; *see also* ECF No. 380 at 47:15-19; ECF No. 483 at
2 11:12-14. But that statement—which referred to *both* “legitimate medical purpose” and “usual
3 course” of “professional practice” (*Ruan*, 597 U.S. at 467)—does nothing to suggest a disjunctive
4 standard.

5 It is thus unsurprising that the Ninth Circuit has not changed its approach in the wake of
6 *Ruan*. *See* ECF 380 at 54-55. To the contrary, just last year, well after the holding in *Ruan*, the
7 Ninth Circuit reaffirmed that the Government is required to prove both prongs. In *United States*
8 *v. Pham*, 120 F.4th 1368 (9th Cir. 2024), the defendant sought to withdraw his guilty plea, claiming
9 that it did not comport with *Ruan*’s requirement that he knowingly issued “unauthorized”
10 prescriptions. *See id.* at 1369-70. The Ninth Circuit disagreed, finding that the guilty plea included
11 admissions by the defendant of knowledge as to “*the elements that made his prescriptions not*
12 *authorized*: he knew the prescriptions were not for a legitimate medical purpose, *and* he knew he
13 was not acting in the usual course of medical practice.” *Id.* at 1371-72 (emphases added).

14 Moreover, since *Ruan*, the Circuit has repeatedly and uniformly upheld instructions that
15 require the Government to prove that both prongs of the authorization test were violated.³ The
16 Manual of Model Criminal Jury Instructions for the District Courts of the Ninth Circuit, which
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18 ³ *See, e.g., United States v. Siao*, 2023 U.S. Dist. LEXIS 201837, at *17, 22-26 (N.D. Cal. Nov. 9,
19 2023), *aff’d*, No. 24-1486, 2025 WL 1009280, at *1 (9th Cir. Apr. 4, 2025) (finding no plain error
20 in giving instruction that “unauthorized manner” means “that the distribution of the controlled
21 substance was outside of the usual course of professional practice *and* without a legitimate medical
22 purpose” and finding that “nothing in *Ruan* directly overruled[ed] *Feingold*.”); *United States v. Kabov*, No. 19-50083, 19-50089, 2023 WL 4585957, at *14-15 n.7 (9th Cir. July 18, 2023)
23 (finding proper the district court’s instructions, “consistent with *Feingold*, that the government
24 was required to prove the distribution was *both* 1) ‘outside the course of professional practice,’ . . .
25 *and* 2) ‘without a legitimate medical purpose.’”) (emphasis added); *United States v. Rand*, 2023
26 U.S. Dist. LEXIS 218784, at *4 (D. Nev. Dec. 7, 2023) (elements of distribution of a controlled
27 substance by a doctor that Government must prove properly stated, in relevant part, as “not for a
28 legitimate medical purpose *and* outside the usual course of professional practice”); *United States v. Patel*, 2023 U.S. Dist. LEXIS 212098, at *8-9 (D. Nev. Nov. 28, 2023) (finding *Ruan* satisfied by defendant’s admission in his plea agreement that he acted “outside the usual course of professional practice *and* not for a legitimate medical purpose”); *United States v. Chisholm*, 2023 U.S. Dist. LEXIS 113956, at *6 (D. Alaska June 30, 2023) (*Feingold*’s articulation of the standard is “not inconsistent with *Ruan*” and the “law in the Ninth Circuit has not meaningfully changed.”).

1 post-dates *Ruan*, also endorses the conjunctive approach. *See id.* at § 12.4 cmt. (9th Cir. Comm.
2 On Model Crim. Jury Instructions 2025). Specifically, the Comment cites *Pham* for the
3 proposition that “a defendant’s ‘admission that he prescribed controlled substances with intent to
4 act outside the usual course of professional practice and without a legitimate medical purpose’ was
5 an admission to the ‘requisite knowledge of the elements that made his prescriptions not
6 authorized,’” thus identifying “outside the usual course of practice” *and* “without a legitimate
7 medical purpose” as the constituent parts of a finding that a defendant acted without authorization.
8 *Id.* (quoting *Pham*, 120 F.4th at 1370-71).

9 Despite all of this authority, the Government urges this Court to chart a new course,
10 asserting that the Ninth Circuit “has not considered the [conjunctive versus disjunctive] issue in
11 light of the [Supreme] Court’s decision in *Ruan*.” ECF No. 380 at 50:17-19. In so doing, the
12 Government effectively asks this Court to assume that the Ninth Circuit repeatedly affirmed
13 challenged instructions without meaningfully considering their implications. But the fact is that
14 *Ruan* simply did not alter the Circuit’s preexisting conjunctive proof requirement, which remains
15 controlling precedent—as the Government effectively concedes in acknowledging that *Ruan* did
16 not address this question. ECF No. 380 at 47:17; ECF No. 483 at 11:12.

17 **b. *Ruan* Has Not Changed Any Other Circuit’s Approach**

18 Because *Ruan* did not address whether the Government must prove knowledge or intent
19 that a medical provider *both* lacked a “legitimate medical purpose” *and* acted outside the “usual
20 course of professional practice,” or convert those criteria into alternative paths to liability, across
21 the Circuits, the treatment of those criteria as conjunctive or disjunctive remains consistent with
22 pre-*Ruan* practice. *See* ECF No. 380 at 54-57. Moreover, the Government’s claim that
23 “overwhelming authority from other Circuits supports the disjunctive” is also incorrect. *See* ECF
24 483 at 12.

25 The Third and Seventh Circuits, like the Ninth, have consistently required the Government
26 to prove lack of authorization in the conjunctive. The Third Circuit, for example, upheld as
27 consistent with *Ruan* jury instructions that required the Government to prove the defendant

1 “knowingly or intentionally distributed controlled substances outside ‘the usual course of
2 professional practice *and* not for a legitimate medical purpose.’” *United States v. Titus*, 78 F.4th
3 595, 602 (3d Cir. 2023) (internal quotation marks omitted and emphasis added). This treatment
4 mirrors the circuit’s pre-*Ruan* approach.⁴

5 The Seventh Circuit, too, has maintained its pre-*Ruan* approach of requiring conjunctive
6 proof. For example, in *United States v. Hofschulz*, the Seventh Circuit cited to pre-*Ruan* authority
7 and held that the “district judge carefully crafted” its instruction requiring proof that the defendants
8 dispensed “‘the controlled substance outside the usual course of professional medical practice, *and*
9 not for legitimate medical purpose.’” 105 F.4th 923, 929 (7th Cir. 2024) (citing *United States v.*
10 *Kohli*, 847 F.3d 483, 489–90 (7th Cir. 2017)). In so holding, the Seventh Circuit found that this
11 standard is “an accurate statement of the law and fully compliant with *Ruan*.” *Id.*⁵

12 Other circuits have reached the same conclusion and have declined to treat *Ruan* as altering
13 their conjunctive articulation of the standard. In the First and Second Circuits, the Government’s
14 burden has been described in conjunctive terms both before and after *Ruan*, with courts after *Ruan*
15 citing pre-*Ruan* authority and continuing to describe the standard in the conjunctive. *See, e.g.*,
16 *United States v. Oladipo*, 2023 U.S. Dist. LEXIS 121268 at *18 (D. Mass. July 14, 2023)

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18 ⁴ See *United States v. Kraynak*, No. 4:17-CR-00403, 2022 WL 3161907, at *3 (M.D. Pa. Aug. 8,
19 2022), aff’d, No. 22-2500, 2023 WL 4636419 (3d Cir. July 20, 2023) (quoting pre-*Ruan* decision
20 in the same case holding that “the Government must prove four things: (1) that [defendant]
21 distributed a mixture or substance containing a controlled substance; (2) that he distributed the
22 controlled substance outside the usual course of professional practice and not for a legitimate
23 medical purpose; (3) that he distributed the controlled substance while knowing or intending that
24 the distribution was outside the usual course of professional practice and not for a legitimate
25 medical purpose; and (4) that the controlled substance was the substance identified in the
26 indictment” and stating that the earlier holding “comports with the Supreme Court’s recent
27 conclusion in *Ruan*”) (emphasis added).

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29 ⁵ In *United States v. Bek*, 493 F.3d 790, 798 (7th Cir. 2007), a pre-*Ruan* case, the jury was
30 instructed in the disjunctive. However, Bek did not challenge that framing either at trial or in the
31 court of appeals. *Id.* Moreover, in addressing his sufficiency challenge, the Seventh Circuit
32 pointed to evidence which “[satisf[ied]] the criminal standard,” including that his conduct was “for
33 other than a legitimate medical purpose” and “outside the course of professional conduct,”
34 suggesting both prongs were sufficiently proven. *Id.* at 799.

1 (articulating standard in conjunctive and quoting the pre-*Ruan* case of *United States v. Sabeau*,
2 885 F.3d 27, 46 (1st Cir. 2018)); compare *United States v. Wexler*, 522 F.3d 194, 206 (2d Cir.
3 2008) (pre-*Ruan*, describing the Government’s burden as proof the defendant caused distribution
4 “other than for a legitimate medical purpose” and “not in the usual course of medical practice”)
5 with *United States v. Parasmo*, 2023 U.S. Dist. LEXIS 15455, at *58-59 (E.D.N.Y. Jan 30, 2023)
6 (finding no error where instruction required finding that defendant “knowingly and intentionally
7 prescribed the controlled substances outside the bounds of professional medical practice and not
8 for a legitimate medical purpose” as “[t]his is precisely what *Ruan* commands.”) (emphasis
9 added).⁶

10 The Sixth Circuit has also required conjunctive proof since *Ruan*. In *United States v.*
11 *Sadrinia*, it addressed a sufficiency challenge and, quoting *Ruan*, explained that “the government
12 was required to prove beyond a reasonable doubt that [the defendant] knew his prescriptions were
13 unauthorized—meaning that they lacked ‘a legitimate medical purpose’ and were outside ‘the
14 usual course of professional practice.’” 134 F.4th 887, 893 (6th Cir. 2025) (quoting *Ruan*, 597
15 U.S. at 454) (emphasis added). The court analyzed the trial evidence separately for each prong.
16 *Id.*⁷

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⁶ At times, the Second Circuit treats the two phrases interchangeably or as evidentiary bellwethers rather than two distinct elements. See, e.g., *United States v. Belfiore*, 2024 U.S. App. LEXIS 11311, at *4 (2d Cir. May 9, 2024) (citing *Ruan* for the proposition that the Government can prove intent “through circumstantial evidence, including by reference to objective criteria such as ‘legitimate medical purpose’ and ‘usual course’ of ‘professional practice’”) (internal quotations omitted). This does nothing to advance the Government’s argument, however, as the Second Circuit has not held that *Ruan* requires a disjunctive interpretation.

⁷ The Sixth Circuit has at various times read 21 C.F.R. § 1306.04’s “legitimate purpose” and “usual course of professional practice” prongs in the disjunctive, conjunctive, and as synonymous phrases, but this muddled practice significantly predates *Ruan* and is not binding on this Court. See *United States v. Bothra*, 2022 U.S. Dist. LEXIS 84971, at *7-13 (collecting cases); see also *United States v. Oppong*, 2022 U.S. App. LEXIS 9475, at *5 (6th Cir. Apr. 8, 2022) (no clear error in instructing jury in the disjunctive when Oppong did not object to the instructions at trial, the Supreme Court had not reached the issue, and Sixth Circuit authority was mixed).

The cases cited by the Government on the other side of the divide only confirm that Ninth Circuit precedent remains untouched by *Ruan* because *Ruan* did not alter preexisting law on the conjunctive/disjunctive question. See ECF No. 483 at 12:10-13:1. The Fifth and Eleventh Circuits have long endorsed a disjunctive reading. See, e.g., *United States v. Lamartiniere*, 100 F.4th 625, 642-43 (5th Cir. 2024) (*Ruan* did not overrule Fifth Circuit precedent using disjunctive language); *United States v. Lubetsky*, 2024 U.S. App. LEXIS 3367, at *3 (11th Cir. Feb. 13, 2024) (finding it remains bound by its holding in *United States v. Aboyan*, 988 F.3d 1288, 1308 (11th Cir. 2021), that the test is disjunctive). And these Circuits have found that *Ruan* addressed the *mens rea* requirement, rather than the “prongs” of the authorization requirement. ECF No. 380 at 55:15-28, 56:1-5; see *Lamartiniere*, 100 F. 4th at 638-42 (finding that *Ruan* was concerned only with the “*mens rea* requirement” of § 841(a)(1) and holding that because *Ruan* did not “unequivocally overrule” the Fifth Circuit’s definition of “authorization,” as previously described in *United States v. Armstrong*, 550 F.3d 382 (5th Cir. 2008), it did not have the authority under the Fifth Circuit’s “rule of orderliness” to “overturn” or “depart” from *Armstrong*’s disjunctive instruction on “authorization”); *United States v. Heaton*, 59 F.4th 1226, 1239, 1241, n. 17 (11th Cir. 2023) (finding that *Ruan* was concerned only with the “*mens rea*” of Section 841(a)(1) and holding that because *Ruan* was not “clearly on point” with respect to the Eleventh Circuit’s disjunctive instruction on authorization, as previously set forth in *Aboyan*, 988 F.3d at 1308, the *Aboyan* instruction remained “binding” precedent on the *Heaton* panel).

The Tenth Circuit’s approach has also remained unchanged. In *United States v. Kahn (Kahn I)*, the Tenth Circuit, following precedent in *United States v. Nelson*, 383 F.3d 1227 (10th Cir. 2004), articulated the authorization standard in the disjunctive, permitting proof of a violation by showing either that the physician acted outside the usual course of professional practice or that the physician acted without a legitimate medical purpose. See 989 F.3d 806, 822 (10th Cir. 2021). The Supreme Court considered *Kahn I* alongside *Ruan*, where the Court found that the jury instructions issued by the district court improperly advised the jury regarding the *mens rea* requirement of § 841(a). *United States v. Kahn (Kahn II)*, 58 F.4th 1308, 1311 (10th Cir. 2023).

1 On remand, the *Kahn II* court explained that the jury instructions were flawed because “without a
2 legitimate medical purpose” was to be assessed from the physician’s subjective perspective, while
3 “outside the usual course of professional practice” was articulated purely as an objective standard.
4 *Id.* at 1316. Because the jury could have convicted under either theory, and *Ruan* forbids
5 conviction under § 841(a) based solely on objectively unauthorized conduct, the instructions were
6 invalid. *See id.* at 1316-17. The Tenth Circuit continued to discuss the authorization standard in
7 the disjunctive but required proof of knowledge and intent with respect to each prong. *See*
8 *generally Kahn II*. Accordingly, *Ruan* did not alter the Tenth Circuit’s use of the disjunctive
9 standard either.

10 At bottom, although the Fifth, Tenth, and Eleventh Circuits permit disjunctive proof, no
11 court has found that *Ruan* requires it. Rather, *Ruan*’s holding is limited to the applicable *mens rea*
12 requirement, and the post-*Ruan* decisions that apply a disjunctive standard simply adhere to prior
13 circuit precedent in that regard. These out-of-circuit decisions have no bearing on this case.

14 Moreover, the Government’s assertion that *Ruan* requires a disjunctive standard is
15 inconsistent with the position it has taken in at least one other post-*Ruan* case. *See, e.g., United*
16 *States v. Parker*, 145 F.4th 915, 919 n.2 (8th Cir. 2025) (jury was instructed on the conjunctive
17 and the Government did not challenge that instruction so court took no position on whether the
18 terms “legitimate medical purpose” and “in the usual course of professional practice” should be
19 considered in the conjunctive or disjunctive). For all of these reasons, there is no basis for this
20 Court to deviate from Ninth Circuit precedent.

21 **c. The Supreme Court Has Not Otherwise Addressed Whether**
22 **the Authorization Clause is Conjunctive or Disjunctive.**

23 Finding no support in *Ruan* or cases applying it, the Government attempts to recast the
24 Supreme Court’s holding in *United States v. Moore*, 423 U.S. 122 (1975), as addressing criminal
25 liability under § 841 solely in terms of “professional practice.” ECF No. 380 at 47:20-25, ECF
26 No. 483 at 11:22-12:5. But as the Supreme Court explained in *Ruan*, “the question in *Moore* was
27 whether doctors could *ever* be held criminally liable under § 841.” *Ruan*, 597 U.S. at 466. *Moore*

1 did not decide the precise contours of the authorization standard. And in any event, *Moore* predates
2 decisions like *Feingold*, which expressly discussed *Moore* in the context of reaching its holding
3 on the requisite conjunctive jury instruction—thereby leaving no doubt that the Ninth Circuit
4 effectively rejected the Government’s interpretation of the Supreme Court’s decision. See
5 *Feingold*, 454 F.3d at 1008; *id.* at 1010 (“The [Supreme] Court … described § 841(a) as prohibiting
6 ‘the significantly greater offense of acting as a drug ‘pusher.’ These statements suggest that the
7 *Moore* Court based its decision not merely on the fact that the doctor had committed malpractice,
8 or even intentional malpractice, but rather on the fact that his actions completely betrayed any
9 semblance of legitimate medical treatment.”) (quoting *Moore*, 423 U.S. at 138).

10 The Government also mischaracterizes *Moore*. Although the Court there focused on the
11 “usual course of professional practice,” *Moore* , 423 U.S. at 124, it also explained that Congress
12 was “particularly concerned with the diversion of drugs from legitimate channels to illegitimate
13 channels,” as the Ninth Circuit underscored in *Feingold*. *Id.* at 135. That understanding
14 necessarily puts at issue whether the drug was distributed for a legitimate medical purpose. In
15 addition, the jury instructions in *Moore* required a finding that Moore distributed methadone “*other*
16 *than in good faith for detoxification* in the usual course of a professional practice and in accordance
17 with the standards of medical practice generally recognized and accepted in the United States.”
18 *Id.* at 138-39 (emphasis added). *Moore* therefore does not support the Government’s position
19 either.

20 **3. The Modifiers “Legitimate” and “Usual” Should Be Removed**

21 In addition to urging this Court to adopt the *Napoli*-based malpractice instruction, and the
22 Ninth Circuit’s conjunctive construction of the legal standard (as the Court’s tentative does), Ms.
23 He also requests (and preserves for review her request) that the Court remove the terms
24 “legitimate” and “usual” from the instructions. *See* ECF 478 at 5-8.

25 In making that request, Ms. He explained that although the Ninth Circuit has approved of
26 instructions containing those modifiers, they are not found in the relevant statutory provisions; the
27 regulation does not state that it defines authorization for purposes of § 841; and the words
28

“legitimate” and “usual” may confuse the jury and dilute the Government’s burden of proof. See ECF 478 at 5-8. In addition, Ms. He explained that both the Ninth Circuit and “the Supreme Court [have] made clear … that a criminal conviction for violating a regulation is permissible only if a statute explicitly provides that violation of that regulation is a crime,” *United States v. Alghazouli*, 517 F.3d 1179, 1184 (9th Cir. 2008)—but Section 841 does not expressly state that the scope of the criminal prohibition may be determined by regulation. See ECF No. 478 at 6.

The Government responds that Ms. He’s argument is “directly contrary” to the Ninth Circuit’s recent decision in *United States v. Keller*, 142 F.4th 645, 655-59 (9th Cir. 2025) (per curiam). ECF No. 483 at 8:13-15. But *Keller* rejected a defendant’s distinct contention that the “charges against him violated the nondelegation doctrine,” 142 F.4th at 650, because the statute failed to provide an “intelligible principle” for the Attorney General to apply, *id.* at 656. The Ninth Circuit reasoned that the Attorney General had been delegated authority to issue regulations under 21 U.S.C. §§ 821 and 871; that the authority was sufficiently “clear and bounded” to satisfy the intelligible principle requirement; and that no heightened intelligible principle standard applies to “regulations relating to criminal penalties.” *Id.* at 658-649.

16 Although *Keller* upheld the use of § 1306.04(a) in a criminal prosecution against a
17 nondelegation challenge, it did not address several of the arguments Ms. He makes here. In
18 particular, it did not cite or discuss *Alghazouli* or the principle that Congress must be clear if it
19 intends for the violation of a regulation to constitute a crime. *See Keller*, 142 F.4th at 656-659;
20 *but see* Appellant’s Reply Br. at 13-14, *United States v. Keller*, No. 23-656 (9th Cir. 2025) (relying
21 on cases applying this principle). Nor did *Keller* address Ms. He’s argument that the words
22 “legitimate” and “usual” could confuse the jury and dilute the Government’s burden of proof
23 because they are evocative of a civil medical care standard to a lay jury. *Keller* thus does not
24 preclude Ms. He’s request here.⁸ In any event, to the extent the Court views *Keller* as foreclosing

25 ⁸ Nor does *Ruan* support the Government’s argument, as it briefly suggests. See ECF No. 483, at
26 8-9. The *Ruan* majority simply “assume[d], as did the courts below and the parties, that a
27 prescription is ‘authorized’ and therefore lawful if it satisfies” the standard in § 1306.04(a). *Ruan*,
597 U.S. at 455.

1 Ms. He's argument that the jury instructions should not include the words "legitimate" and "usual,"
2 Ms. He respectfully preserves this argument for further review.

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4 Dated: November 8, 2025

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5

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